BAF

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s): G.J. Gormley et al.

Application Number: 10/010,678 Case No.: 19109DE

Filing Date: December 7, 2001

Title of the Invention: TRANSDERMAL TREATMENT WITH 5-ALPHA-REDUCTASE INHIBITORS *(as amended)*

Examiner: V. Y. Kim

Art Unit: 1618

SUPPLEMENTAL APPEAL BRIEF

This Appeal Brief is being re-submitted in view of the Notification of Non-Compliant Appeal Brief under 37 CFR 41.37, mailed October, 16, 2006, having a response date of November 16, 2006. Please note that the "Summary of Claimed Subject Matter" section has been amended.

Please charge deposit account 13-2755 for fees due in connection with this appeal brief. If any time extensions are needed for the timely filing of the present appeal brief, Appellants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

37 C.F.R. 1.8 Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450, on the date appearing below.

MERCK & CO., INC.

By _____ Date November 2, 2006

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REAL PARTY IN INTEREST

The real party in interest is Merck & Co., Inc., of Rahway, New Jersey, by assignment recorded at the U.S. Patent and Trademark Office on April 26, 1996 (Reel 7916/Frame 0548). The inventors of the present application assigned their interests to Merck & Co., Inc., in an assignment executed April 25, 1994.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to the Appellants, or known to Appellants' legal representative, that will directly affect the Board's decision in the pending appeal, other than the earlier appeal in the present application, Appeal No. 2004-0543, decision mailed December 29, 2004.

STATUS OF CLAIMS

Claims pending: 28-37.

Claims cancelled: none.

Claims allowed: none.

Claims rejected: 28-37.

Claims on appeal: 28-37.

STATUS OF AMENDMENTS

An amendment under 37 CFR 1.116 was filed June 24, 2005, in response to and subsequent to the May 6, 2005, final rejection. This amendment was not entered as the Examiner contended it raised new issues requiring further consideration and/or search, because the claims were narrowed and could require a new search. This is referred to as the "fifth amendment" in the description below.

One preliminary amendment and four amendments were filed for this application. A preliminary amendment was filed on December 7, 2001, accompanying a new divisional application under 37 CFR 1.53(b) based on parent Application Serial No. 09/699,906. A second amendment under 37 CFR 1.111 was filed October 16, 2002. The two amendments were entered by the Examiner. Subsequently, A third amendment under 37 CFR 1.116 was filed April 25, 2003, (following a Final Office Action), but was never entered by the Examiner because the Examiner stated it raised new issues that would require further

consideration and/or search. A Notice of Appeal was timely filed April 25, 2003, and a Decision on Appeal (Appeal No. 2004-0543) was mailed December 29, 2004. The Decision on Appeal raised a new ground of rejection under 37 CFR 41.50(b)(1), for which an amendment (the fourth) was timely filed January 27, 2005. The list of claims presented in Appendix I reflects entry of these amendments. A fifth amendment under 37 CFR 1.116 was filed June 24, 2005, in response to the May 6, 2005, final rejection. This amendment was not entered as the Examiner contended it raised new issues requiring further consideration and/or search, because the claims were narrowed and could require a new search.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention as defined in Claims 28-32 under appeal relates to a method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor. In particular, independent Claim 28 reads:

- A method of treating androgenic alopecia [page 3, lines 2-3]
- consisting essentially of [transition phrase]
- transdermally administering [page 6, line 31 to page 7, line 2]
- to a person in need of such treatment [page 3, line 5, ("patient" not "person"), original Claim 1, page 15, lines 4-5 ("person")]
- a therapeutically effective amount [page 7, lines 13-15]
- of a 5alpha-reductase 2 inhibitor [page 3, lines 5-6, lines 15-17]

The invention defined in Claims 33-35 under appeal relates to a method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one. Support for independent Claim 33 is found in the original specification follows:

- A method of treating androgenic alopecia [page 3, lines 2-3]
- consisting essentially of [transition phrase]
- transdermally administering [page 6, line 31 to page 7, line 2]
- to a person in need of such treatment [page 3, lines 5 - "patient" not "person"; original claim 1, page 15, lines 4-5, original Claim 11, page 17, line 2 ("person").
- a therapeutically effective amount [page 7, lines 13-15].
- of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one. [page 2, lines 10-11; page 4, line 23; original Claim 11, page 17, lines 2-3]

The invention defined in Claims 36-37 under appeal relates to a transdermal skin patch comprising a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor. Support for independent Claim 36 is detailed below:

- A transdermal skim patch [page 6, line 33]
- consistently essentially of [transition phrase]
- a therapeutically effective amount [page 7, lines 13-15]
- of a 5alpha reductase 2 inhibitor [page 3, lines 5-6, lines 15-17]
- as the active ingredient. [page 6, line 15, page 7, lines 20-21].

A copy of the claims appears in the CLAIMS APPENDIX.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There is one issue being presented for review by the Board of Appeals. The issue on appeal is the rejection of Claims 28-37 under 35 U.S.C. § 103(a) as being unpatentable over Goldman, US 5,407,944. Appellants believe the rejection to be erroneous, as will be explained in the Argument Section that follows.

ARGUMENT

I. Claims 28 to 37 are not obvious under 35 U.S.C. § 103(a) as being unpatentable over US 5,407,944.

As set forth in detail below, Appellants submit that the methods for treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one as defined by Claims 28, 29 and 31-34, the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, in a transdermal skin patch, as defined by Claims 30 and 35, and the transdermal skin patch consisting essentially of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient as defined by Claims 36 and 37, are nonobvious over the cited references. Applicants submit that the Board of Appeals should reverse the Examiner's rejections of Claims 28-37. Favorable action by the Board is respectfully requested.

A. The § 103 (a) Obviousness Rejection of Claims 28,29 and 31-34 over US 5,407,944 is Improper

Claims 28, 29 and 31-34 specify that the method of treating androgenic alopecia consists essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor. US 5,407,944 to Goldman teaches a method for promoting hair growth comprising administering a therapeutically effective amount of at least two active agents. These active agents are selected from vasodilators, estradiols, 5alpha-reductase inhibitors and salts, esters and prodrugs thereof. US 5,407,944 does not teach or even suggest the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha reductase inhibitor. Indeed, in the only exemplification in US 5,407,944, the 5alpha-reductase inhibitor is used in prophetic examples (1) with a vasodilator and estradiol, in a 3 ingredient treatment (US 5,407,944 col. 8, line 68-col. 9, line 2) and (2) with a vasodilator and a 5alpha-reductase inhibitor in a 2 ingredient combination (Ibid., col. 9, lines 3-4).

Contrary to the Examiner's contention, the expression "consisting essentially of" does not permit additional active ingredients, such as vasodilators and estradiol. Consisting essentially of excludes other elements from having any essential significance to the combination. The additional ingredients in US 5,407,944 useful for growing hair are elements that would have essential significance in the combination. "Consisting essentially of" permits a degree of "reading on" additional unspecified substances which do not affect the basic and novel characteristics of the claimed invention. See, Practicing Law Institute, Landis On Mechanics of Patent Claim Drafting, 1997, § 8. However, additional active ingredients do affect the basic characteristics of the claimed invention and are not encompassed by the presently drafted claims.

B. The § 103 (a) Obviousness Rejection of Claims 30 and 35 over US 5,407,944 is Improper

Claims 30 and 35 depend from Claims 28 and 31, respectively, further distinguish the present invention and add the limitation that the 5alpha-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, is administered via transdermal patch. US 5,407,944 does not teach or suggest administration of a 5alpha-reductase inhibitor via transdermal patch. US 5,407,944 does describe several formulations in the patent; namely:

(1) Minoxidil as a topical solution (col. 3, lines 39-52);

(2) Minoxidil in tablet form (col. 3, lines 53-62);

(3) Nitroglycerin as a transdermal system (col. 4, lines 1-6);

(4) Diazoxide as a capsule or suspension (col. 4, lines 7-18);
(5) Nifedipine as a capsule (col. 4, lines 19-38);
(6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
(7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5,line 28);
(8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);
(9) Finasteride as a tablet (col. 5, lines 43-62).

Of the nine formulations listed above from the US 5,407,944 patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the US 5,407,944 patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The US 5,407,944 patent at col. 6, lines 10 to 50, does not teach a transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g., 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), as asserted by the Examiner. In fact, read in context with the particular formulations US 5,407,944 teaches in the patent, US 5,407,944 teaches away from the administration of a 5alpha-reductase inhibitor via transdermal skin patch.

C. The § 103 (a) Obviousness Rejection of Claims 36 and 37 over US 5,407,944 is Improper

Claims 36 and 37 are directed to a transdermal skin patch consisting essentially of a 5alpha reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient. US 5,407,944 does not teach or suggest a transdermal skin patch consisting essentially of a 5alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient.

Goldman does not teach or suggest formulation of a 5alpha-reductase inhibitor in a transdermal patch. Goldman does describe several formulations in the patent; namely:

(1) Minoxidil as a topical solution (col. 3, lines 39-52);
(2) Minoxidil in tablet form (col. 3, lines 53-62);
(3) Nitroglycerin as a transdermal system (col. 4, lines 1-6);
(4) Diazoxide as a capsule or suspension (col. 4, lines 7-18);
(5) Nifedipine as a capsule (col. 4, lines 19-38);
(6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
(7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5,line 28);
(8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);

(9) Finasteride as a tablet (col. 5, lines 43-62).

Of the nine formulations listed above from the US 5,407,944 patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the US 5,407,944 patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The US 5,407,944 patent at col. 6, lines 10 to 50, does not teach a transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g., 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), as the Examiner stated. In fact, read in context with the particular formulations US 5,407,944 teaches in the patent (cited above), US 5,407,944 teaches away from the transdermal skin patch consisting essentially of a 5alpha-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient.

CONCLUSION

Appellants request that the Board of Patent Appeals and Interferences reverse the outstanding rejections of claims 28 to 37.

Please charge deposit account 13-2755 for fees due in connection with this appeal brief. If any time extensions are needed for the timely filing of the present appeal brief, appellants petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

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CLAIMS APPENDIX

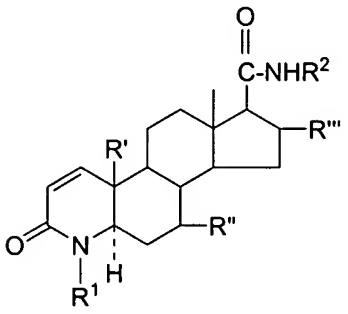
The claims on appeal are as follows:

Claim 28. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

Claim 29. The method according to Claim 28, wherein androgenic alopecia is male pattern baldness.

Claim 30. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

Claim 31. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula I:



I

or a pharmaceutically acceptable salt thereof wherein:

R^1 is hydrogen, methyl or ethyl;

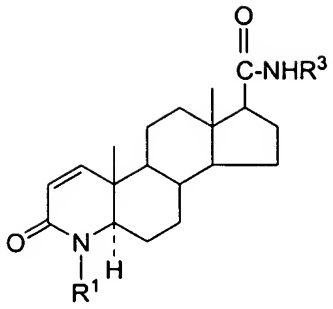
R^2 is a hydrocarbon radical selected from straight and branched chain alkyl of from 1-12 carbons or monocyclic aryl optionally containing 1 or more lower alkyl substituents of from 1-2 carbon atoms and/or 1 or more halogen substituents selected from Cl, F and Br;

R' is hydrogen or methyl;

R" is hydrogen or β-methyl; and

R''' is hydrogen, α-methyl or β-methyl.

Claim 32. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula II:



II

or a pharmaceutically acceptable salt thereof, wherein:

R^1 is hydrogen or methyl; and

R^3 is branched chain alkyl of from 4 to 8 carbons.

Claim 33. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

Claim 34. The method of Claim 33 wherein androgen alopecia is male pattern baldness.

Claim 35. The method according to Claim 33, wherein the 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one inhibitor is transdermally administered by a transdermal skin patch.

Claim 36. A transdermal skin patch consisting essentially of a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor as the active ingredient.

Claim 37. The transdermal skin patch according to Claim 36 wherein the 5alpha-reductase 2 inhibitor is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

EVIDENCE APPENDIX

No evidence is provided by the appellant.

RELATED PROCEEDINGS

1. Board of Patent Appeals and Interferences Decision on Appeal No. 2004-0543, Application No. 10/010,678